REMARKS

Status of the Application and the Present Amendment

Claims 8-10 and 21-28 are pending and stand rejected in the application. With entry of this amendment, claims 22 and 26 have been canceled without prejudice, and claims 8, 9, 21, and 25 have been amended. Claims 8 and 9 have been further amended to recite a larger number of contiguous nucleotides of SEQ ID NO 1. Additional support for the amendment is provided in the specification, e.g., at page 33, lines 26-33. Dependent claims 21 and 25 have also been amended to recite larger numbers of contiguous nucleotides of SEQ ID NO 1.

Applicant submits that the claim amendments are made to improve clarity or more clearly claim Applicant' invention. The claim cancellation and amendments should not be viewed as acquiescence of any ground of rejection. Applicants believe no new matter has been added by the amendments.

The following remarks address issues raised in the Office Action mailed April 2, 2002.

Rejections under 35 U.S.C. 101 and 35 U.S.C. 112, 1st Paragraph

Claims 8-10 and 21-28 remain rejected as allegedly lacking patentable utility. Applicant has previously traversed the rejection. Applicant pointed out that, contrary to the assertions of the Office, the subject specification has disclosed patentable utility in the present application that is substantial, specific, and credible. Applicant also noted that the disclosed utilities were further confirmed and experimentally verified in peer viewed publications. In response, the instant Office Action stated that the publications which confirmed the utilities of the subject invention could not be taken into account due to their post-filing publication dates. The Office Action further stated that at the time the application was filed the utility was not established and that the functional relationship between IL-B30 with IL-23p40 was not

disclosed in the specification. Applicant respectfully traverses the instant rejection for the reasons stated below.

1. Legal standard of the utility requirement

In rejecting the presently claimed invention, the Office Action has apparently taken the position that only conclusive evidence substantiated by actual experimental data would establish patentable utilities. However, such is not the legal standard for the utility requirement.

First, according to the MPEP (§ 2107.02 III-A), a disclosed utility corresponding to the claimed subject matter satisfies the utility requirement under § 101 absent evidence which would cast doubt on the objective truth of the disclosed utility. There is no legal requirement that the disclosed utility must be supported by conclusive experimental results. The MPEP has noted that several judicial decisions "direct the office to presume that a statement of utility made by an applicant is true." As quoted in the MPEP:

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope. [MPEP§ 2107.02-III-A; quoting *In re Langer*, 503 F.2d 1380 (CCPA 1980), at 1391; emphasis original]

The MPEP has also cautioned that "office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical filed of the invention or for other general reasons." Rather, "any inquiry must start by asking if there is any reason to question the truth of the statement of utility" (MPEP § 2107.02-III-A; at page 2100-39).

The MPEP specifically noted that "applicant does not have to provide evidence sufficient to establish that an asserted utility is true 'beyond a reasonable doubt'" and that "nor

must an applicant provide evidence such that it establishes an asserted utility as a matter of statistical certainty." See, MPEP § 2107.02-VII. The MPEP further states that "evidence will be sufficient if, considered as a whole, it leads a person of ordinary skill in the art to conclude that the asserted utility is more likely than not true" (MPEP § 2107.02-VII; emphasis original).

In addition, with respect to therapeutic or pharmaceutical utilities, the MPEP indicates that a reasonable correlation between the evidence and the asserted utility is sufficient. As noted in the MPEP, the courts "have routinely found evidence of structural similarity to a compound known to have a particular therapeutic or pharmaceutical utility as being supportive of an assertion of therapeutic utility for a new compound" (MPEP § 2107.03-II; emphasis added).

Further, with respect to the "credible" prong of the utility requirement, the MPEP states that the determination is "whether the assertion of utility is believable to a person of ordinary skilled in the art based on the totality of evidence and reasoning provided." The MPEP further notes that "an assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion" (MPEP § 2107.02-III-B). Moreover, even if the Office has provided evidence showing that one of ordinary skill in the art would doubt the asserted utility (which has not been provided by the Examiner in the instant case), the applicant can nonetheless submit rebuttal evidence sufficient to convince such a person of the invention's asserted utility (MPEP § 2107.02-V; at page 2100-42).

Finally, Applicant notes that, as stated in the MPEP, "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101 and 35 U.S.C. 112; additional statements of utility, even if not credible," do not render the claimed invention lacking in utility" (MPEP § 2107.02-I; at page 2100-37; emphasis added).

2. Reiteration of utilities disclosed in the specification

In maintaining the instant rejection, the Office Action overlooked the utilities that were actually disclosed in the present invention. Other than the structural similarities

between IL-B30 and other members of the long chain cytokines, the specification also disclosed that IL-B30 could modulate receptor function as receptor ligands (see, e.g., Col. 11, lines 43-49). The specification taught that IL-B30 can be involved in various cellular activities including inflammation (e.g., Col. 25, lines 55-62), which is supported by actual experimental data disclosed in the specification. For example, the specification sets forth actual data which demonstrate that IL-B30 is differentially expressed in a number of immune active cells, including activated macrophages or activated dendritic cells (see, page 56, lines 23-29). These experimental data indicate that IL-B30 is at least useful as a marker for these immunologically important cell types. It was also disclosed in the specification that IL-B30 polypeptides and nucleic acids can be useful for identifying novel cytokine receptors or screening modulators of other cytokines and their receptors (pages 49-50). Such utilities are undoubtedly substantial because they define real world uses of the claimed subject matter.

The subject specification also taught how to make use of and experimentally confirm the disclosed utilities. As explained in more detail in Applicant's previous response, the specification specifically taught how to assay expression level of IL-B30 in various human and mouse cell types (see, e.g., pages 53-59). The specification also taught that IL-B30 can be involved in various cellular activities including inflammation (see, page 56, lines 23-29). The specification further taught how to experimentally examine other biological functions of IL-B30 (pages 61-64). For example, the specification provided detailed procedures for one to assay effects of IL-B30 on cytokine production (e.g., page 62) or peripheral blood mononuclear cell proliferation (e.g., page 63). Clearly, such disclosures of the subject application are specific because they are specific to the subject matter being claimed.

Further, as detailed below, the disclosed utilities are also credible. First, the subject disclosures as well as knowledge known to the skilled artisans are more than sufficient to satisfy the "more likely than not true" test. In addition, as previously noted, the disclosed utilities of the subject invention were experimentally confirmed by peer reviewed publications. These publications demonstrated that IL-30B can indeed bind to cytokine receptors and regulates immune responses, and that altered levels of IL-B30 correlates with a number of

cellular activities. Significantly, these published studies all employed substantially the same methods and assays as described in the subject specification. This strongly indicates that the utilities as disclosed in the subject invention would be regarded as credible by the skilled artisans.

3. Analysis of the instant rejection

Applicant submits that the Office Action appeared to have adopted an incorrect standard in maintaining the instant rejection. The Office did not meet the initial burden as required by the MPEP (see, e.g., MPEP § 2107.02-IV) in providing evidence to establish a prima facie showing that the claimed invention lacks utility, i.e., evidence that the skilled artisans would question the objective truth of the disclosed utilities. In traversal of the rejection, Applicants will address the following points.

a) references cited by the Office do not meet the burden

In maintaining the rejections, the Examiner cited to several references (i.e., Skolnick et al., Tibtech 18:34-39, 2000; and Bork et al., Cur. Opin. Struc. Biol. 8:331-332, 1998) as support for the proposition that amino acid sequence homology cannot necessarily predict the function of proteins. However, Skolnick et al. and Bork et al. are clearly not evidence that the logic underlying the asserted utility is seriously flawed or that the facts upon which the asserted utility is based are inconsistent with the logic underlying the assertion. These two references at most suggest that homology-based functional predictions may not always be accurate. By no means did these references establish that in any given case, sequence homology based functional prediction cannot be "more likely than not true." These references, as well as the other assertions made in the Office Action, certainly cannot refute the actual data disclosed in the specification which substantiate the disclosed utilities of IL-B30 (e.g., differential expression data indicative IL-B30 being a marker of activated macrophages and dendritic cells).

b) utilities are supported by, not disclosed in, the post-filing publications

In addition, Applicant has provided in the previous response publications which experimentally confirmed the utilities disclosed in the subject specification (Wiekowski et al., J. Immunol., 166: 7563-70, 2001; and Oppmann et al., Immunity, 13: 715-25, 2000). The Examiner said that these publications could not be taken into account because they were published subsequent to filing of the subject application. In response, Applicant points out that Applicant did not cite to Wiekowski et al. and Oppmann et al. as disclosure of utilities of the subject invention. Rather, they were provided as additional evidence that the utilities already disclosed in the subject specification are substantial and credible. Also, as discussed above, the MPEP clearly indicates that Applicant is entitled to further evidence to rebut any assertion of a lack of utility. The law does not exclude post-filing publications as additional evidence that the utilities already disclosed in the patent application is substantial, specific, and more importantly in the instant case, credible. Rather, the MPEP specifically states that "there is no predetermined amount or character of evidence" an applicant can provide to support an asserted utility, . . ." (MPEP § 2107.02-VII).

Further, while the references cited by the Examiner relate to the general technical fields, Wiekowski et al. and Oppmann et al. provided scientific evidence specific to the subject invention. Clearly, the general proposition noted in Skolnick et al. and Bork et al. cannot refute the specific and actual evidence reported in Wiekowski et al. and Oppmann et al. which confirmed the utilities of IL-B30 as disclosed in the subject invention. The fact the latter employed substantially the same assays and methods as disclosed in the subject specification simply indicate that the disclosed utilities are credible. In light of such actual and specific evidence, it is wholly improper for the Office to resort to a *per se* unpredictability position in dismissing the disclosed utilities of the subject specification.

c). post-filing publications do not conflict with the disclosed utilities

With respect to the disclosure in the post-filing publications that IL-B30 is a subunit of IL-23, the Examiner noted that such functional relationship was not disclosed in the specification. As discussed above, Applicant needs only to disclose one patentable utility in order to satisfy the utility requirement. It is not necessary for Applicant to disclose all possible utilities or biological function of the IL-B30 protein. In the present case, Applicant has disclosed in the specification various utilities of IL-B30. For example, the specification teaches that IL-B30 can play a role in inflammation and a number of other cellular activities (see, page 56, lines 23-29). This is precisely what was experimentally confirmed in the published reports. Specifically, one of previously submitted publications, Wiekowski et al. (J. Immunol., 166: 7563-70, 2001), demonstrated that expression of IL-B30 indeed induces multiorgan inflammation (see, e.g., the title and abstract). Therefore, the functional properties of IL-B30 disclosed in the subject specification clearly satisfy the utility requirement.

Applicant further notes that the teachings of Wiekowski et al. and Oppmann et al. by no means conflict with the utilities disclosed in the subject specification. While Wiekowski et al. and Oppmann et al. disclosed that IL-B30 is a subunit of IL-23, it does not follow that IL-B30 standing alone does not have a functional property that can give rise to a patentable utility. Nowhere in the cited publications suggest that IL-B30 has to be complexed with other subunits of IL-23 in order to be functional or biologically active. To the contrary, Wiekowski et al. clearly indicate that just alternating IL-B30 expression levels could lead to various cellular and immunological responses in vivo. Such is one of the disclosed utilities of the subject invention, substantial, specific, and credible.

Moreover, even assuming that IL-B30 indeed has to be complexed with IL-12p40 in order to be functional in vivo, this at most relates to the underlying mechanism of the disclosed utility. It is well established that an applicant does not need to show the underlying mechanism of his invention in order to obtain a patent on his invention. Therefore, non-disclosure of IL-B30 being a subunit of IL-23 is simply immaterial to the issue of whether IL-B30 has a patentable utility.

Finally, as noted above, Applicants are required to disclose no more than one patentable utility. Therefore, even assuming for the sake of discussion that some of the disclosed utilities are indeed inconsistent with the post-filing publications, other utilities of the subject invention (e.g., elevated IL-B30 expression being a marker of activated macrophages) can nonetheless still satisfy the utility requirement.

For all of the reasons stated above, it is submitted that the present invention has disclosed patentable utilities that are substantial, specific, and credible. Accordingly, Applicant respectfully requests that the instant rejection be withdrawn.

Rejections under 35 U.S.C. 112, second paragraph

Claims 22, 26, and 28 were rejected as allegedly being indefinite. The ground for the rejections is that "a broad or limitation together with a narrow range or limitation that falls within the broad range or limitation is considered indefinite." The Office Action noted that "claims 21 and 25 recite the broad recitation '120 contiguous nucleotides of SEQ ID NO: 1'" and that "claims 22 and 26 recite narrower statement '140, 175, 200 or 300 contiguous nucleotides of SEQ ID NO: 1.'" Similarly, with respect to the rejection of claim 28, the Office Action stated that "claim 27 recites '17 contiguous nucleotides of SEQ ID NO: 3'" and that "claim 28 recites '25, 45, 55 or 6o contiguous nucleotides of SEQ ID NO: 3.'"

With due respect, Applicant notes that the instant rejections appear to have been misplaced. This is because the prohibition against the use of a narrow numerical range that falls within a broader range only applies to situations where both the broad range and the narrow range are recited in the same claim (see, e.g., MPEP § 2173.05(c)-I). In the instant case, as noted by the Examiner, the broad ranges are respectively recited in claims 21, 25, and 27, while the narrower ranges are specified in claims 21, 26, and 28, respectively.

Further, claims 22, 26, and 28 depend from claims 21, 25, and 27, respectively. A dependent claim necessarily encompass a narrower claim scope than a claim from which it depends. Here, it is natural and necessary that claims 22, 26, and 28 recite narrower ranges so that they encompass narrower claim scopes as compared to claims 21, 25, and 27, respectively.

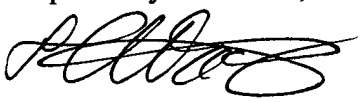
Applicant submits that there is no indefiniteness in the noted claim limitations and request that the instant rejections be withdrawn. Should the Examiner choose to maintain the rejections, Applicant respectfully requests clarification.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400 x 5209.

Respectfully submitted,



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Appendix: Clean version of claims under examination

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Clean Version of All Pending Claims
(claims unamended herewith appear in small font)

8. (Three times amended) A method for the detection of a polynucleotide, comprising contacting said polynucleotide with a probe that hybridizes, under stringent wash conditions of at least 65°C, less than about 150 mM salt, to:

a) at least 394 contiguous nucleotides of the open reading frame of SEQ ID NO: 1; or

b) at least 17 contiguous nucleotides of the open reading frame of SEQ ID NO: 3;

to form a duplex, wherein detection of said duplex indicates the presence of said polynucleotide.

9. (Three times amended) A kit for the detection of a polynucleotide, comprising a compartment containing a probe that hybridizes, under stringent hybridization wash conditions of at least 65°C, less than about 150 mM salt , to:

a) at least 394 contiguous nucleotides of the open reading frame of SEQ ID NO: 1; or

b) at least 17 contiguous nucleotides of the open reading frame of SEQ ID NO: 3;

to form a duplex, wherein detection of said duplex indicates the presence of said polynucleotide.

10. The kit of claim 9, wherein said probe is detectably labeled.

21. (Twice amended) The method of claim 8 wherein said probe hybridizes to at least 394 contiguous nucleotides of said open reading frame of SEQ ID NO: 1.

23. (Previously amended) The method of claim 8 wherein said probe hybridizes to at least 17 contiguous nucleotides of said open reading frame of SEQ ID NO: 3.

24. (Previously amended) The method of claim 23 wherein said probe hybridizes to at least 25, 35, 55, or 60 contiguous nucleotides of said open reading frame of SEQ ID NO: 3.

25. (Twice amended) The kit of claim 9 wherein said probe hybridizes to at least 394 contiguous nucleotides of said open reading frame of SEQ ID NO: 1.

27. (Previously amended) The kit of claim 9 wherein said probe hybridizes to at least 17 contiguous nucleotides of said open reading frame of SEQ ID NO: 3.

28. (Previously amended) The kit of claim 27 wherein said probe hybridizes to at least 25, 45, 55, or 60 contiguous nucleotides of said open reading frame of SEQ ID NO: 3.